

1.4 510(k) Summary of Safety and Effectiveness

Submitted by: Herbert Crane
Manager, Regulatory Affairs

Address: Nobel Biocare USA LLC
22715 Savi Ranch Parkway
Yorba Linda, CA 92887

Telephone: (714) 282-4800, ext. 7830

Facsimile: (714) 282-9023

Date of Submission: February 2, 2005

Classification Name: Endosseous Implant (21 CFR 872.3640)

Trade or Proprietary
or Model Name: Groovy Implants

Legally Marketed Device(s): Nobel Biocare Endosseous Implants (K041661)

Device Description:

Nobel Biocare Groovy Implants are threaded, root-form dental implants intended for use in the upper and/or lower jaw to support prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function to partially or fully edentulous patients.

Nobel Biocare Groovy Implants incorporate a groove on the implant thread and are machined from titanium. Groovy Implants are available straight or tapered, and have a surface treatment consisting of a thin, uniform titanium oxide layer (TiUnite®). Groovy Implants may be placed in the oral cavity using either a single stage surgical procedure or a two stage surgical procedure. If a single stage procedure is used, the implants may be immediately loaded following insertion where good initial stability of the implant can be obtained.

The design of the Nobel Biocare Groovy Implant incorporates a groove on the implant thread. Bone is formed more rapidly within the groove compared with other parts of the implant, resulting in faster integration of the implant. The bone formation within the groove results in a mechanical interlock, which gives the implant increased stability compared with implants without the groove. These properties will be of special importance when placing implants in soft bone in posterior regions or whenever immediate or early loading is applied.

Indications for Use:

Nobel Biocare's Groovy Implants are root-form endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's Groovy Implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare Groovy Implants may be placed immediately and put into immediate function providing that the initial stability requirements detailed in the surgical manuals are satisfied.

Groovy implants are indicated for use in soft bone in posterior regions or whenever immediate or early loading is applied. The Groovy implants incorporate a groove on the implant thread and are preferred over models without the groove in these soft bone indications because bone forms more rapidly in the groove than on other parts of the implant resulting in increased stability when compared to non-grooved implants.



APR 19 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nobel Biocare AB
C/O Mr. Herbert Crane
Manager, Regulatory Affairs
Nobel Biocare USA, LLC
22715 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K050258
Trade/Device Name: Groovy Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: February 2, 2005
Received: February 3, 2005

Dear Mr. Crane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

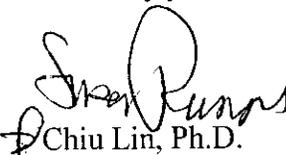
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

1.3

Indications for Use

510(k) Number (if known):

Device Name: Groovy Implants

Indications For Use:

Nobel Biocare's Groovy Implants are root-form endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's Groovy Implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare Groovy Implants may be placed immediately and put into immediate function providing that the initial stability requirements detailed in the surgical manuals are satisfied.

Groovy implants are indicated for use in soft bone in posterior regions or whenever immediate or early loading is applied. The Groovy implants incorporate a groove on the implant thread and are preferred over models without the groove in these soft bone indications because bone forms more rapidly in the groove than on other parts of the implant resulting in increased stability when compared to non-grooved implants.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

Page 1 of 1

510(k) Number: K050258